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Different therapeutic mechanisms of rigid and semi-rigid mandibular repositioning devices in obstructive sleep apnea syndrome☆

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ABSTRACT

To clarify the mechanisms of rigid and semi-rigid mandibular repositioning devices (MRDs) in obstructive sleep apnea syndrome (OSAS), seven and 13 patients received rigid and semi-rigid MRDs, respectively. Each patient underwent polysomnographic and computed tomographic examinations at the initial consultation and after symptom improvement. Three-dimensional models of the upper airway (hard palate level to epiglottic base) were reconstructed by image processing software (Mimics version 14.2) to measure airway morphology. The mean age and body mass index were 58.1 years and 24.8 kg/m^2, respectively, in the rigid MRD group and 57.9 years and 23.2 kg/m^2, respectively, in the semi-rigid MRD group. The apnea-hypopnea index significantly improved ($P < 0.05$, Wilcoxon signed-rank test) from 22.0 to 8.9 and 20.5 to 11.5 events per hour of sleep in the respective groups. The cross-sectional areas measured at the epiglottic tip (from 2.0 to 2.6 cm^2) and hard palate (from 2.6 to 3.3 cm^2) levels also increased in the respective groups ($P < 0.05$). However, airway volume, cross-sectional area measured at the uvular tip level, and anteroposterior and transverse diameters of the airway were not significantly different. In conclusion, both types of MRDs improve respiratory status, but they affect different parts of the airway.

1. Introduction

Obstructive sleep apnea syndrome (OSAS) is the most common sleep-related breathing disorder and a potentially life-threatening condition. Patients with OSAS have increased risk of hypertension, myocardial infarction, cardiac failure, arrhythmia, and cerebral apoplexy (Hamilton et al., 2004). Therapeutic methods include surgery (Barrera et al., 2007; Gerbino et al., 2014; Schendel and Powell, 2007), continuous positive airway pressure (CPAP), and oral appliance (OA) therapy (Kushida et al., 2006a, 2006b; Aurora et al., 2010).

According to the American Academy of Sleep Medicine (Kushida et al., 2006b), OAs are indicated in patients with primary snoring and upper airway resistance syndrome, patients with mild-to-moderate obstructive sleep apnea (OSA) who prefer OAs to CPAP, and those with severe OSA who refuse CPAP. OAs can be classified into mandibular repositioning devices (MRDs) (Ellis et al., 2003) and tongue-retaining devices (TRDs) (Higurashi et al., 2002). These devices are further subdivided on the basis of their design (Ihara et al., 2011), including the type of construction material, configuration, type and location of the coupling mechanism, degree of customization, and amount of vertical opening and lateral jaw movement permitted. As these factors can influence the clinical outcome, they should be considered when applying research-based evidence to clinical practice.

MRDs are the most common type of OAs (Chan et al., 2007). Rigid (Blanco et al., 2005; Lam et al., 2007; Hoekema et al., 2008; Petri et al., 2008; Aarab et al., 2011) and semi-rigid (Tan et al., 2002; Nakano et al., 2013) MRDs are mainly used in the clinical setting. The literature includes several reports of these devices, but their therapeutic mechanisms remain unclear. The purpose of this prospective, nonrandomized clinical study was to clarify the mechanisms of rigid and semi-rigid MRDs in OSAS.

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2. Material and methods

2.1. Subjects

The study included 20 patients (16 men and four women) with OSAS at Yamaguchi University Hospital. The patients treated from September 2009 to March 2010 used semi-rigid MRDs ($n = 13$), and those treated from March 2010 to April 2012 used rigid MRDs ($n = 7$). The two types of devices were not randomly assigned, but based on a date of their first visit.

2.2. MRDs

The rigid MRD consisted of two parts fixing the mandible in a forward position (Fig. 1a). Edge-to-edge occlusion was maintained to avoid side effects such as temporomandibular disorders (TMDs) (Rose et al., 2001; Ferguson et al., 2006; Kushida et al., 2006b; Doff et al., 2012).

The semi-rigid MRD comprised upper and lower elements joined by plastic straps from the maxillary canine to the mandibular molar regions. It permitted only forward movement of the mandible and prevented reduction of the airway during mouth opening. This appliance is generally not associated with side effects such as TMDs (Tan et al., 2002; Nakano et al., 2013), so the mandible was advanced further than the edge-to-edge occlusal position (Fig. 1b).

2.3. Polysomnographic examination

Each patient underwent polysomnography (Alice 5 diagnostic sleep system, Philips Respironics, Best, The Netherlands) at the initial consultation and after symptom improvement. The apnea-hypopnea index (AHI), apnea index (AI), hypopnea index (HI), and lowest oxygen saturation (SpO_2) were measured. Apnea was defined as complete cessation of airflow for 10 s and hypopnea was defined as a 50% reduction in oronasal airflow lasting for 10 s with atleast 3% desaturation. The AHI was calculated as the number of apnea and hypopnea events per hour of sleep (Kushida et al., 2006b).

2.4. CT examination

Computed tomography (CT) was also performed twice in each patient: at the initial consultation and after symptom improvement. Multislice helical examinations of the upper airway were performed with holding their breath in supine position, to reproduce the sleep-related breathing condition, in a CT scanner (SOMATOM Definition, Siemens AG, Erlangen, Germany). The slice thickness was 0.6 mm. The scans were three-dimensionally reconstructed with image processing software (Mimics version 14.2, Materialize NV, Leuven, Belgium) for analysis.

The superior and inferior boundaries of the airway were located at the levels of the hard palate and base of the epiglottis, respectively. The lateral and posterior boundaries were the pharyngeal walls. The anterior boundary was defined by the soft palate, base of the tongue, and anterior wall of the pharynx. The following airway morphologic parameters were measured in the reconstructed images: airway volume and cross-sectional areas and maximum anteroposterior and transverse diameters at the levels of the hard palate, tip of the uvula, and tip of the epiglottis (Fig. 2).

2.5. Statistical analysis

Data are presented as means ± standard deviations (SD). The Wilcoxon signed-rank test in statistical software (JMP 9.0, SAS, Cary, NC) was used for all comparisons. $P < 0.05$ was considered significant.

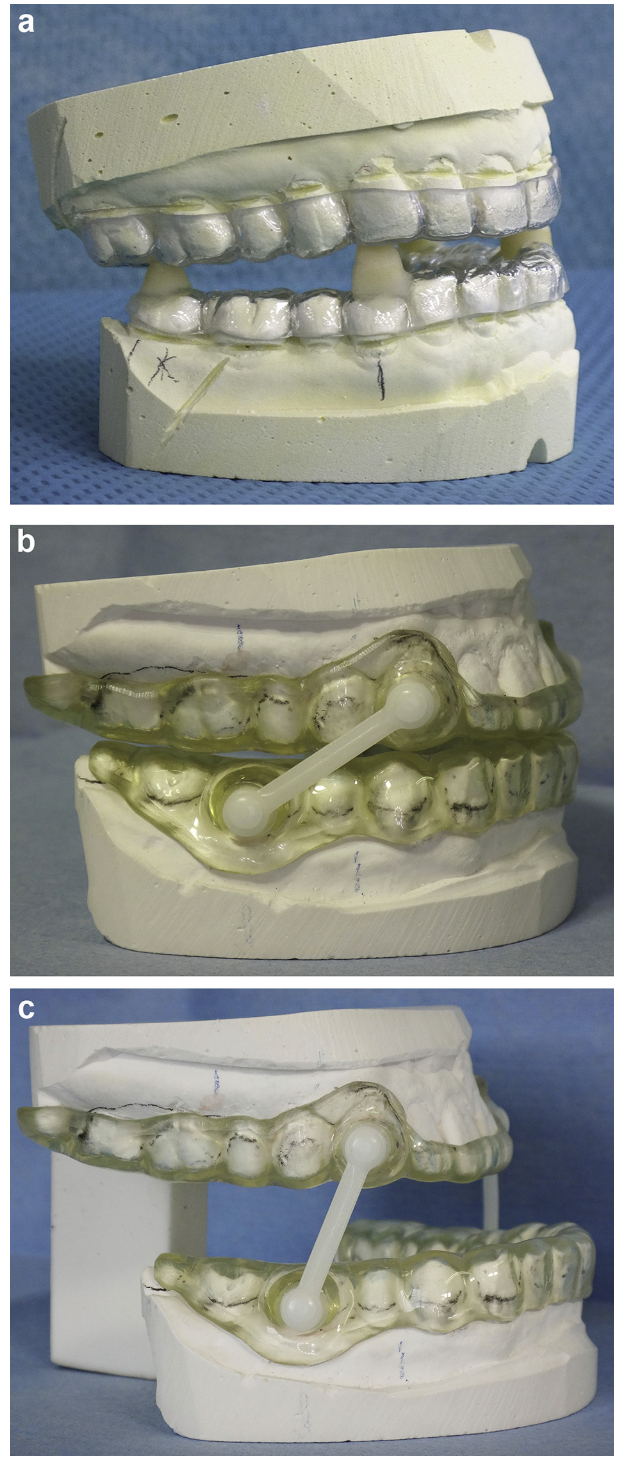

Fig. 1. The (a) rigid, (b) semi-rigid MRDs at closing and (c) at opening used in this study.

3. Results

3.1. Initial assessment

The mean age and body mass index (BMI) were 58.1 years and 24.8 kg/m^2 in the rigid MRD group and 57.9 years and 23.2 kg/m^2 in the semi-rigid MRD group, respectively. The mean AHI, AI, HI, and lowest SpO_2 were 22.0, 7.1, and 10.1 events per hour of sleep and

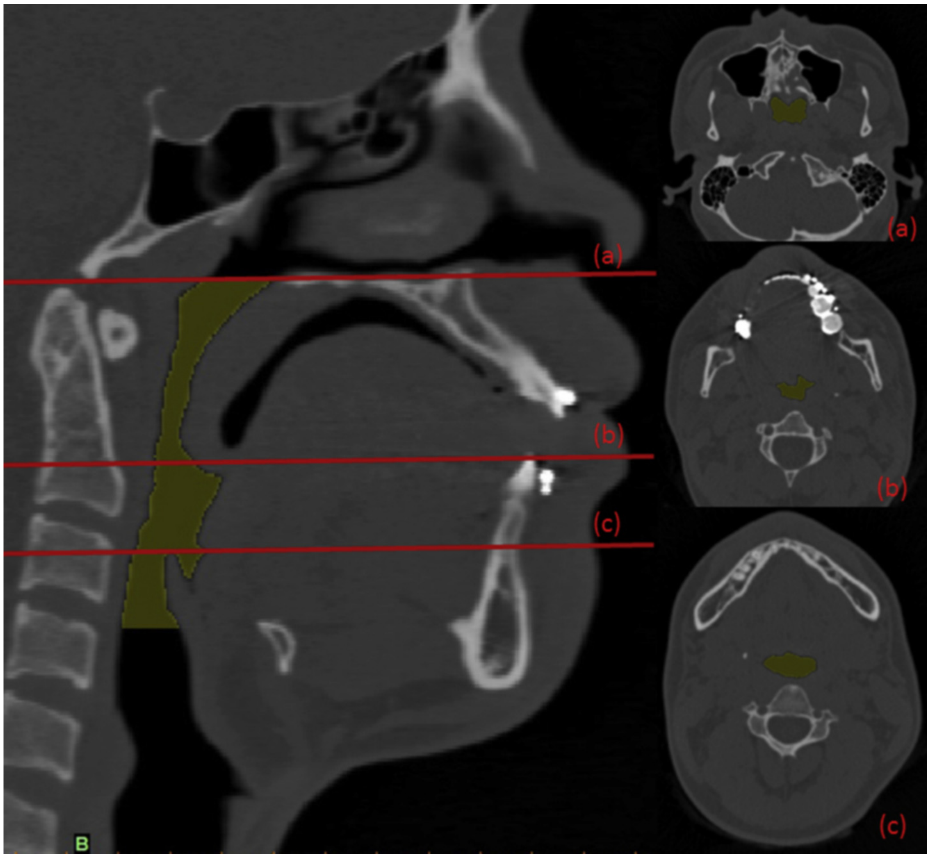

Fig. 2. Air-mode CT images (sagittal and axial views) of a patient with OSAS showing the landmarks used for airway morphologic measurements. a) Area at the hard palate level, b) area at the uvular tip level, c) area at epiglottic tip level.

81.6%, respectively, in the rigid MRD group and 20.5, 7.9, and 12.9 events per hour of sleep and 84.2%, respectively, in the semi-rigid MRD group (Table 1). The groups showed no significant differences in any of these parameters.

3.2. Symptom improvement

The mean AHI significantly improved to 8.9 and 11.5 events per hour of sleep and the mean AI improved to 3.1 and 2.4 events per hour of sleep in the rigid and semi-rigid MRD groups ($P < 0.05$), respectively, during the treatment. Only the semi-rigid MRD group showed significant improvements ($P < 0.05$) in the mean HI and lowest SpO_2 (Table 2).

The cross-sectional areas measured at the levels of the epiglottic tip and hard palate significantly increased in the rigid and semi-rigid MRD groups, respectively. No significant differences in the other morphologic measurements were observed (Table 3).

4. Discussion

In this study, we investigated the changes in airway form induced by MRDs. Use of the rigid and semi-rigid MRDs significantly increased the cross-sectional areas of the airway at the tongue base and soft palate levels, respectively, implying that these devices act at different sites. The differences are attributable to structural variations in the MRDs: the rigid MRD moves the mandible forward and fixes its position, thereby repositioning the hyoid bone and tongue anteriorly to maintain airway patency (Liu et al., 2000), whereas the semi-rigid MRD advances the mandible and permits mouth opening to prevent airway obstruction.

Okushi et al., (2011) endoscopically found that an average mandibular advancement of 13 mm significantly increases the airway space because of palatoglossal and palatopharyngeal muscle contraction and soft palate enlargement. The significant increase in the cross-sectional area at the hard palate level in the semi-rigid MRD group may also be explained by their findings (Ferguson

Table 1
Baseline characteristics (mean ± SD [range]) of the rigid and semi-rigid MRD groups.

Variable	Rigid MRD group ($n = 7$)	Semi-rigid MRD group ($n = 13$)
Male-to-female ratio	6:1	10:3
Age (years)	58.1 ± 7.6 (44–68)	57.9 ± 11.4 (36–76)
BMI (kg/m^2)	24.8 ± 3.6 (18.9–30.7)	23.2 ± 2.7 (19.4–28.5)
AHI (events/h)	22.0 ± 13.8 (12.8–50.3)	20.5 ± 8.5 (7.2–41.5)
AI (events/h)	7.1 ± 6.2 (0.5–17.4)	7.9 ± 8.6 (0.3–32.7)
HI (events/h)	10.1 ± 9.0 (0.3–28.7)	12.9 ± 5.9 (2.5–21.8)
Lowest SpO_2 (%)	81.6 ± 4.7 (74–89)	84.2 ± 6.1 (67–93)

Table 2
Comparison of the polysomnographic indices (mean ± SD) between the initial consultation and after symptom improvement in the study groups.

Variable	Rigid MRD group ($n = 7$)			Semi-rigid MRD group ($n = 13$)		
	Before	After	P	Before	After	P
AHI (events/h)	22.0 ± 13.8	8.9 ± 6.5	*	20.5 ± 8.5	11.5 ± 7.9	*
AI (events/h)	7.1 ± 6.2	3.1 ± 5.7	*	7.9 ± 8.6	2.4 ± 3.1	*
HI (events/h)	10.1 ± 9.0	4.6 ± 1.6	NS	12.9 ± 5.9	8.4 ± 5.9	*
Lowest SpO_2 (%)	81.6 ± 4.7	85.7 ± 9.9	NS	84.2 ± 6.1	89.3 ± 3.9	*

*$P < 0.05$ by the Wilcoxon signed-rank test.

Table 3
Comparison of the airway morphologic measurements (mean ± SD) between the initial consultation and after symptom improvement in the study groups.

Variable	Rigid MRD group ($n = 7$)			Semi-rigid MRD group ($n = 13$)		
	Before	After	P	Before	After	P
Airway volume (cm^3)	11.6 ± 2.7	13.6 ± 4.2	NS	10.7 ± 4.7	11.4 ± 6.9	NS
Hard palatal level						
Cross-sectional area (cm^2)	3.3 ± 2.4	3.3 ± 2.4	NS	2.6 ± 1.9	3.3 ± 1.9	*
Anteroposterior diameter (cm)	1.9 ± 1.3	1.9 ± 1.3	NS	1.6 ± 1.1	1.8 ± 0.9	NS
Transverse diameter (cm)	1.8 ± 1.3	1.9 ± 1.3	NS	1.6 ± 1.1	2.2 ± 1.1	*
Uvular tip level						
Cross-sectional area (cm^2)	1.7 ± 0.5	1.7 ± 0.9	NS	1.3 ± 0.6	1.5 ± 1.0	NS
Anteroposterior diameter (cm)	1.4 ± 0.3	1.3 ± 0.5	NS	1.2 ± 0.3	1.2 ± 0.6	NS
Transverse diameter (cm)	2.5 ± 0.6	2.5 ± 1.0	NS	2.0 ± 0.9	2.3 ± 1.1	NS
Epiglottic tip level						
Cross-sectional area (cm^2)	2.0 ± 0.8	2.6 ± 1.1	*	2.2 ± 1.4	2.2 ± 1.6	NS
Anteroposterior diameter (cm)	1.2 ± 0.3	1.5 ± 0.5	NS	1.2 ± 0.4	1.2 ± 0.4	NS
Transverse diameter (cm)	2.8 ± 0.7	3.1 ± 0.9	NS	2.6 ± 1.0	2.5 ± 1.0	NS

*$P < 0.05$ by the Wilcoxon signed-rank test.

et al., 2006; Kushida et al., 2006b). If the amount of mandibular advancement were increased beyond edge-to-edge occlusion in the rigid MRD group, similar results to those of the Okushi et al., (2011) study might have been obtained.

In a previous study, mouth opening reduced the distance between the mandible and the hyoid bone, resulting in backward movement of the hyoid bone and narrowing of the area at the level of the base of the tongue (Lee et al., 2007). However, we did not observe significant narrowing in this region with the semi-rigid MRD. Patients with OSAS using semi-rigid MRDs would not show backward positioning of the tongue because of the mandibular advancement and opening.

Doff et al., (2012) have reported that the risk of developing a temporomandibular disorders (TMDs) appears limited with long term OA use. In the present study, neither the change of the occlusion nor TMDs occurred in the both groups. On the other hand, Tan et al., (2002) have suggested possibility with a few side effects of the semi-rigid MRD, but did not reach clear conclusions because of small sample size. As for the indication and contraindication such as TMDs for the OAs, further examination is necessary.

OAs have a reported therapeutic efficiency of about 50–80% in mild-to-moderate OSAS (Hoffstein, 2007), and they may be effective even in severe cases (Johal et al., 2005). Approximately 40 kinds of OAs are currently available (Ihara et al., 2011), but they are rarely used on the basis of their site of action. Within the limitations of this study, including the nonrandomized design and small sample size, we conclude that both rigid and semi-rigid MRDs improve respiratory status in patients with OSAS, but they affect different parts of the airway. Therefore, the therapeutic efficiency of MRDs in OSAS can be improved if they are applied according to their site of action.

5. Conclusions

The mechanisms of rigid and semi-rigid MRDs in OSAS were compared by using polysomnographic and CT examinations. The apnea-hypopnea index significantly improved ($P < 0.05$) in the both groups. The cross-sectional areas measured at the epiglottic tip and hard palate levels also increased significantly in the rigid MRD and the semi-rigid MRD group, respectively ($P < 0.05$). However, airway volume, cross-sectional area measured at the uvular tip level, and anteroposterior and transverse diameters of the airway were not significantly different. In conclusion, both types of MRDs improve respiratory status, but they affect different parts of the airway.

Conflict of interest

None declared.

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